REMARKS

In the most recently received (final) Official Action mailed June 7th, 2006, the Patent Examiners of record have stated a single rejection basis: previously pending claims 1-3 and 6-8 respectively are again rejected under 35 USC 102(b) as being anticipated by the Vaillancourt '138 patent [U.S. Patent No. 5,591,138].

In response, applicant has taken the following actions:

(α) Applicant has canceled claims 1-3 and 7-8 respectively, without prejudice.

(β) Applicant has amended dependent claim 6.

(6) Applicant has added new independent claims 9-10 respectively.

Accordingly, via the present claim cancellations, claim amendments and newly added independent claims, as well as by the discussion presented hereinafter, applicant believes he has overcome and obviated the single basis for rejection stated by the Examiners in the most recently received (final) Official Action.

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I. The Need To Submit A Request For Continued Examination Pursuant To 37 CFR 1.114.

The instant substantive Response is submitted pursuant to 37 CFR 1.114 as part of the requested continued examination of the instant application. The submission and formal entry of this Amendment and Response into the prosecution file history and official record is therefore made as a matter of legal right by applicants and their undersigned attorney.

However, applicant and his undersigned attorney maintain and affirm that there was no substantive cause why the most recently received Official Action mailed June 7th, 2006 should have been a final action; and in applicants' opinion, there are both good and sufficient reasons why the most recently received Official Action should not have been a final action. The stated grounds for rejection were presented previously by the Examiners; and applicant could have overtly and directly addressed the Examiners' views and position without introducing any new issues or raising additional questions. Such differences as existed between the Examiners' stated views and applicant's proffered claims could have been more easily identified and understood; and the common ground shared by the Examiners and applicants employed as a basis for resolution of disputes. Thus, there was no substantive point to be made nor advantage to be had by their imposition of

a final status for the instant Office Action.

B. Applicant and his undersigned attorney have, as a matter of formal record, previously stated their intentions. It remains still our express desire and purpose to advance the prosecution of the instant application on the merits, and not to delay or hinder its progress unnecessarily.

Accordingly, via this Amendment and Response, applicant substantively speaks to the single issue stated by the instant (final) Official Action. Accordingly, applicant now presents newly added independent claims 9-10 respectively and currently amended dependent claim 6, which clearly define and particularly delineate applicant's invention as unique subject matter having substantial patentable merit.

Concomitant with the instant claim cancellations, claim amendments and new claim additions, applicant will also directly address and review in detail the single basis for rejection stated by the Examiners in the instant (final) Official Action.

II. The Examiners' Stated Views And Position For Rejecting The Pending Claims

A. The Examiners have again rejected the previously pending claims; and in support of their rejection, the Examiners have stated their views and position at Pages 2-3 in the Official Action - but this statement does not either recognize or seriously consider the definitional wording, recited limits and essential structural features of the instant invention itself. In short, the reasons stated by the Examiners for their rejection of the previously pending claims wrongly concentrate on the conventional, over emphasize the irrelevant, and markedly distort the value of the commonplace.

Applicants also respectfully submit and maintain that the evaluation and the determination conducted by the Examiners has meaningfully and effectively ignored the subject matter as a whole which constitutes applicant's invention. The Examiners' views, as expressed at Pages 2-3 of the Official Action, unfortunately reveal the following flaws: (a) The Examiners have not conducted any true consideration of the essence of applicant's invention, as defined by the wording of the previously pending claims; (b) the Examiners appear have lost focus of what applicant's invention really is and what constitutes its essential parts; (c) the Examiners have concentrated upon the existence of certain conventional features present within known intravenous needle-catheter assemblies which are

structurally shared and commonly present among them; and (d) the Examiners have not supported their views with specific facts or direct evidence from the prior art, but instead have pointed vaguely and elusively to certain prior art figures which are neither demonstrative nor illustrative of relevant facts.

In consequence, applicant maintains that the Examiners' given reasons and stated rationale have become lost in the very verbiage which sets forth merely the overall fundamental design and conventional features commonly shared by many different intravenous needle-catheter assemblies generally. Thus the recitation of conventionally known elements in the claim language - *i.e.,* (i) a needle safety container; (ii) a needle housing unit; (iii) a piercing needle; and (iv) various auxiliary items related to the use or positioning of a piercing needle, such as an internal flash chamber - has distracted the Examiners' attention to the degree where the very essence and definition of applicant's invention has been forgotten and ignored.

As one noteworthy example of such confusion, the Examiners have overemphasized the existence as well as distorted the function of pre-positioned radial and axial cutouts - structural features which are well known, conventionally employed and frequently present in the wall of a needle safety container. Rather than accept such conventionally positioned radial and axial cutouts for what they are - discrete guidance aids for

improving the movement and travel of a needle safety container within a needle housing unit - the Examiners have instead used the recognized functions provided by such pre-positioned cut outs as a pretext for and linkage to finding the existence of " a configured spool section comprising a tab-engagement segment and at least one notch for on-demand engagement" [see Page 3, 3rd paragraph of the Official Action].

B. Despite all these matters, applicant and his undersigned attorney have neither desire nor purpose to initiate a needless and pointless quarrel with the Examiners concerning the mode and manner by which they performed their evaluation. Such a quarrel would only create rancor and acrimony.

To the contrary, it remains our goal to prosecute the present invention purposefully and effectively. In order to achieve that end, applicant and his undersigned attorney believe that a markedly altered definition and a more pointed recitation of the essential elements comprising the present invention would be of far more value than mere argument. Applicant reiterates his position: he seeks only to advance and not hinder the substantive prosecution of the instant application.

For these reasons, applicant and his undersigned attorney have canceled independent claims 1-2 and 7-8 respectively, as well as dependent claim 3, which were pending previously; and added new independent claims 9-10 as a substitute definition and more precise recitation of the subject matter as a whole comprising applicant's invention. Moreover, to avoid a repetition of the sort appearing in the most recently received Official Action, a brief summary of newly added independent claims 9-10 is provided below for the Examiners' benefit.

C. It will be noted and appreciated that newly added independent claims 9 and 10 respectively are presented as "Jepson" type claims. In this style of claiming, a recitation of those features conventionally known in the relevant prior art is made within the claim's preamble. In this manner, each of the following items is identified as being known in the prior art:

a hollow, elongated needle-safety container of set dimensions and configuration which presents at least one discrete wall and has an open front end adapted for passage there through by the tip of a piercing needle;

a hollow needle housing of fixed dimensions and configuration which has at least one discrete wall, open front and rear ends, and is moveably mounted upon the needle-safety container; and

a piercing needle disposed co-axially within the interior of the needle housing.

Equally important, applicant's present invention is explicitly identified by new independent claims 9 and 10 as an "improvement of an on-demand needle retaining and locking mechanism". The instant invention is thus an improved structure for an on-demand needle retaining and locking mechanism in a needle-catheter assembly; and, by such definition, intimately points out that other devices in fact exist within the relevant prior art which can and do serve as a retaining and locking mechanism. However, since the instant invention is an improvement over previously known kinds of retaining and locking mechanisms, the Jepson claims overtly and precisely set forth the elements, limitations and features - definitionally and structurally - that readily distinguish and separate the invention from all previously existing retaining and locking mechanisms.

Accordingly, newly added independent claims 9 and 10 each recite what are the novel and unforeseen structural elements, limitations and features which comprise the improved on-demand retaining and locking mechanism. Thus, as recited explicitly by claim 9, these are:

A needle-safety container which (i) is radially rotable by hand on-demand; and (ii) has a sized solid tab member disposed at and extending

radially from said open front end at an aligned position.

A hollow collar which (1) is rotably attached to the open front end of the needle safety container; (2) presents at least one discrete wall of preset dimensions and configuration, and a central void space; (3) has open front and rear ends adapted for passage there through of the tip of a piercing needle; and (4) has a solid tab member disposed on and extending radially from said rotable collar at an aligned position.

A needle housing which (a) is adapted for slidable axial movement at will over said rotable needle-safety container; and (b) has a slidable configured spool section joined to the front end of the needle housing for on-demand engagement with said solid tab member of said rotable collar, said configured spool section comprising a central cavity, open front and rear ends adapted for passage there through by a piercing needle, a flanged rib, a tab-engagement segment, and at least one notch disposed within said tab engagement segment,

wherein said configured spool section is alignable at will with and can be engaged by and disengaged from said solid tab member of said rotable collar on-demand.

Complementing claim 9, newly added independent claim 10 recites a slight different and alternative definition of similar structural elements, limitations and features.

It will be appreciated that the definitions recited by newly added independent claims 9 and 10 clearly state and explicitly point out where the solid tab member is located and positioned on the needle-safety container; specify where the hollow collar is positioned and what are its capabilities; and explicitly place a slidable spool section having unique structural components and functional capabilities at the front end of the needle housing. Applicant respectfully submits that it is these explicitly recited components which define, demonstrate and prove the novelty and distinctiveness of the improved on-demand needle retaining and locking mechanism constituting the present invention.

III. The Present Rejection Under 35 USC 102(b)

The Examiners have again rejected the previously pending claims under 35 USC 102(b) as being anticipated by the Vaillancourt '138 patent reference [U.S. patent No. 5,591,138]. In support of their rejection, the Examiners have stated their views and position at Pages 2-3 of the Official Action.

Accordingly, applicants believe useful to summarize what are the multiple legal obligations of the Examiners.

A. The Requisite Legal Standards And Requirements

1. Presentation Of A *Prima Facie* Case

The Examiners are legally obliged to present a *prima facie* case and to support factually each and every basis for rejection which is made. The requirement and burden of presenting a *prima facie* case is a procedural tool of patent application examination; and demands that facts or other probative evidence be shown to exist within the relevant prior art that would reasonably allow and support the conclusion that is the underlying rationale for rejection [see for example, *In re Piasecki*, 223 USPQ 785 (Fed. Cir. 1984) and the cases internally cited therein].

The Examiners can satisfy this requirement and legal burden only via an objective and specific showing that the prior art of record actually provides such information and knowledge; and also demonstrates that persons of ordinary skill in the pertinent art had public access to and awareness of such information and knowledge. Should the Examiners fail to present a *prima facie* case, there is neither adequate support or justification for any rejection basis as a matter of law.

2. Anticipation

As a matter of long established law, anticipation under 35 USC 102(b) requires exact identity of the claimed article within a conventionally known device or apparatus existing previously in the prior art. Each required element or essential component of the claimed article of manufacture (including each specific feature and limitation defining the invention as a whole) must be described or embodied, directly or indirectly, within a single reference [Richardson v. Suzuki Motor Co., 9 USPQ2d 1913 (Fed. Cir. 1989)].

Moreover, the single prior art reference of record must describe the claimed subject matter with sufficient clarity and detail to establish that the subject matter existed in the prior art. Thus, the reference must describe applicant's claimed invention sufficiently to have placed a person of ordinary skill in the field in possession of it [Akzo N.V. v. U.S. Int'l Trade Comm'n, 1 USPQ2d 1241 (Fed. Cir 1986)]; and that such prior existence of the claimed invention would be recognized by persons working in the field of the invention [In re Spada, 15 USPQ2d 1655 at 1657 (Fed. Cir. 1990)].

Also, in deciding the issue of anticipation, the Examiners must identify each requisite element and limitation recited within applicant's claims; determine their meaning in light of the description provided by the Specification; and identify the existence and presence for each of the

corresponding elements and limitations within the disclosure of the allegedly anticipating reference [Scripts Clinical and Research Foundation vs. Genetech Inc., 18 USPQ2d 1001 (Fed. Cir. 1991); Glaverbel Society Anonyme vs. Northlake Marketing and Supply Inc., 35 USPQ2d 1496 (Fed. Cir. 1995)].

3. Non-Obviousness

In addition, although not yet employed by the Examiners as a basis for rejection, it is deemed useful here also to identify the proper legal basis and standard for determining obviousness under 35 USC 103(a). Where applicant's claimed subject matter could be rejected as obvious in view of a single prior art reference (or a combination of two or more different references), a proper analysis must consider *inter alia* two factors: (I) whether the prior art of record would have suggested to those of ordinary skill in the art that they should make the claimed article; and (ii) whether the prior art would also have revealed that in so making, those of ordinary skill would have a reasonable expectation of success [In re Dow Chemical Company, 5 USPQ2d 1529 (Fed. Cir. 1988)]. Both the suggestion and the reasonable expectation of success must be found directly within the text of the prior art reference(s) itself and cannot be derived or extrapolated from applicant's disclosure [In re Vaeck, 20 USPQ2d 1438 (Fed. Cir. 1991)].

In addition, the same inquiry must be carried out in the context of a purported "obvious modification" of the prior art information. The mere fact that the prior art might be modified in any proposed manner does not make that modification obvious unless and until the prior art overtly suggested the desirability of the modification [In re Fritch, 23 USPQ2d 1780 (Fed. Cir. 1992) and the references cited therein].

B. The Examiners Have Failed to Present A Prima Facie Case:

The Examiners have again employed the Vaillancourt '138 patent [U.S. patent No. 5,591,138] as the basis for the anticipation rejection. Applicant, however, respectively submits that the Examiners views and conclusions as stated in the instant Official Action do not provide an adequate factual basis for rejection of the present invention - particularly as now defined by newly added independent claims 9 and 10 respectively.

Applicant and his undersigned attorney also submit and affirm that the Examiners' previous mode and manner of attempting to substantiate and support their views, by referring merely to certain figures within the Vaillancourt '138 patent, is factually inadequate as well as legally improper and impermissible. In short, applicant maintains that the Examiners have

failed to present a *prima facie* case of anticipation to date.

As noted above, the Examiners are overtly and legally obliged to show that each required element or essential component of applicant's claimed article of manufacture exists in the prior art; and this obligation demands that each specific element, limitation and feature of applicant's claimed invention as a whole must be clearly identified, described or embodied within a single cited reference of record.

Applicants maintains that the Examiners' evaluation technique (as employed in the final Official Action) does not support their views with specific facts or direct evidence from the prior art reference - but instead points only vaguely and elusively to certain figures in the cited reference. This mode of explanation is neither demonstrative nor illustrative of relevant facts; and does not identify applicant's claimed subject matter with sufficient clarity or adequate detail to establish that the claimed subject matter existed in fact within the prior art. The Examiners thus did not perform their legal duty properly and failed to present a *prima facie* case of anticipation via the Vaillancourt '138 patent.

Applicant further submits that a proper and detailed review of the factual content actually disclosed by the single cited and applied prior art reference, the Vaillancourt '138 patent, amply reveals the substantive

factual deficiencies in the Examiners' stated position.

C. The Factual Content of the Vaillancourt '138 Patent Reference

1. The Vaillancourt invention is an improved needle assembly which prevents needle sticks. The invention discloses a protective sheath for shielding a hypodermic needle; and uses a simple arrangement for biasing the sheath into an extended locked position in order to prevent accidental puncture [see Column 1, lines 1-21 and lines 57-67].

2. The protected needle assembly used to prevent needle sticks must employ not less than four requisite and essential components: a housing component, a distinct rigid tube component, a needle mounted in the housing and extending through the rigid tube, and a retractable sheath which is disposed over the needle. The sheath is movable longitudinally over the rigid tube and needle between an extended position covering the needle, and a retracted position exposing the needle [Column 2, lines 3-12; Column 6, lines 10–14].

3. In particular, as shown by Figs. 1-6 respectively and stated by the Vaillancourt '138 patent, the housing is employed for the mounting of a

syringe or other needle structure [see Column 5, lines 61-66]; the rigid tube is of cylindrical shape and is used to grasp the assembly [see Column 5, lines 66-67; and Column 6, lines 1-2]; and the sheath is telescopically mounted within the rigid tube and is disposed around the needle in a protective relationship [see Column 6, lines 5-8].

4. The component parts of the structural mechanism by which the Vaillancourt needle assembly can be moved from a retracted position into an extended and locked position are also explicitly revealed by Figs. 1-6 respectively and described in detail by the '138 patent. These component parts are: (i) The sheath must provide at least one projection which extends outwardly from the external surface [Column 2, line 13; column 6, lines 29-31]; (ii) the rigid tube must provide a guide slot of specified configuration to receive the projection extending from the sheath [Column 2, lines 24-31; Column 6, lines 29-31]; and (iii) a coiled spring must be present within the rigid tube in order to bias the sheath as it moves from a retracted position to an extended position [Column 6, lines 15-22].

5. Equally important, the '138 patent explicitly requires that the structural mechanism by which the Vaillancourt needle assembly can be moved from a retracted position into an extended and locked position

present specific features as part of the guide slot within the rigid tube of the Vaillancourt assembly. As clearly illustrated by Figs 1-5 respectively, these are: a circumferentially directed slot portion for receiving the projection extending from the sheath when the sheath is in an extended position; a longitudinally directed slot portion; and an inclined slot portion (V-shaped) at the proximal end of the rigid tube to receive and retain the projection when the sheath is in the retracted position [Column 6, lines 31-39; Column 2, lines 24-31].

6. The Vaillancourt '138 patent also describes how the structural mechanism for biasing and locking the needle assembly is to be used. As disclosed therein, when the projection on the sheath lies within the circumferential slot portion of the rigid tube, the sheath cannot be moved from the extended position. Thus, in order to use the needle assembly, the face of the sheath is brought against the skin of the patient; and the rigid tube is rotated slightly such that the projection extending from the sheath becomes displaced into and moves within the longitudinally directed slot portion of the guide slot. The continued pressure on the housing causes the rigid tube to slide telescopically forward over the sheath, and concomitantly causes the needle to enter into the patient [Column 2, lines 31-46].

Subsequently, when the projection reaches the end of the longitudinally directed slot portion, the pressure on the assembly is released. However, the residual stress causes the sheath to rotate again within the rigid tube, thereby causing the projection of the sheath to move into the V-shaped inclined slot portion of the guide slot. This second sheath rotation and overt movement of the projection into the V-shaped inclined slot portion serves to lock the sheath in the retracted position [Column 2, lines 47-57; Column 6, lines 40-60].

This factual summary accurately presents the sum and substance of the information disclosed by the Vaillancourt '138 patent.

D. The Major Differences Existing Between Applicant's Claimed Invention And The Vaillancourt '138 Patent:

Applicant respectfully submits and maintains that there are many major differences and marked distinctions between the instant invention defined by the presently amended claims and the subject matter disclosed by the Vaillancourt '138 patent reference. Among them are the following:

1. The structural mechanism by which the Vaillancourt needle assembly can be moved from a retracted position into an extended and

locked position explicitly requires three component parts: A sheath which provides at least one projection which extends outwardly from the external surface; a rigid tube which provides a guide slot of specified configuration to receive the projection extending from the sheath; and a coiled spring placed within the rigid tube in order to bias the sheath as it moves from a retracted position to an extended position.

In contrast, the present invention makes no such demands whatsoever. The improved on-demand needle retaining and locking mechanism defined by the currently pending claims does not require any guide slots configured to receive a projection from a sheath, nor use a coiled spring to bias a sheath as it moves from a retracted position to an extended position.

2. The Vaillancort '138 patent demands that the structural mechanism by which the needle assembly can be moved from a retracted position into an extended and locked position present specific features as part of the guide slot within the rigid tube of the Vaillancourt assembly. These are: a circumferentially directed slot portion for receiving the projection extending from the sheath when the sheath is in an extended position; a longitudinally directed slot portion; and an inclined slot portion (V-shaped) at the proximal end of the rigid tube to receive and retain the projection when the sheath is

in the retracted position.

Notably, applicant's claimed invention does not require and does not specify the presence of a circumferentially directed slot portion, or a longitudinally directed slot portion, or an inclined slot portion within guide slot. Instead, applicant's improved on-demand needle retaining and locking mechanism does not employ or utilize any guide slots at all.

3. The Vaillancort '138 patent employs a singular working relationship among its three requisite component parts to place the assembly into a locked position. Two separate and individual rotations must be performed: First, the rigid tube must be rotated initially in order to cause the projection of the sheath to enter into the longitudinally disposed slot portion. Second, the sheath must be rotated subsequently in order that the projection then be moved into the V-shaped inclined slot portion. Thus, it is only by performing two different and distinct rotations in sequence that the sheath can become locked in the retracted position.

In contradistinction, applicant's claimed invention employs and utilizes an entirely unique and radically different locking mechanism structure compared to that demanded by the Vaillancort '138 patent. As presently claimed, the locking structure comprises two entities: a sized solid tab member disposed on and extending from the exterior of the needle-safety

container; and a configured spool section present as part of a needle housing, is alignable at will with the tab member, and is able to engage, retain and disengage the tab member on-demand. Neither of these unique inter-locking structural elements are shown or suggested by the disclosure of the Vaillancort reference.

D. The Conclusions Of The Examiners:

As a consequence of the factual review for the Vaillancort '138 patent and its comparison with the currently claims of the instant invention, applicant respectfully affirms that the views and conclusions stated by the Examiners concerning the issue of anticipation are factually unsupported and clearly erroneous. As demonstrated above, a range and variety of major differences and distinctions exist between the information and knowledge taught by the Vaillancort '138 patent and applicant's claimed invention.

Applicant therefore respectfully submits that the Examiners have not properly recognized the limited informational content and requisite structural requirements for the structural mechanism disclosed by the Vaillancort reference; and have unfortunately overlooked the restricted scope and constrained value of the operational mechanism by which to bias the sheath as it moves from a retracted position to an extended position as is explicitly taught by the cited reference of record.

Moreover, applicants maintain that the Examiners have unfortunately wrongly chosen to extrapolate only certain items and over-emphasize the value of specified details from the totality of information disclosed by the Vaillancort '138 patent; and have misapplied the true value of these extrapolated items, particularly as regards the structural elements and particular limitations now required by a guide slot having a circumferentially directed slot portion, and a longitudinally directed slot portion, and an inclined slot portion - as required by the Vaillancort reference.

Applicant further submits and maintains that a slidable configured spool section joined to the front end of the needle housing for on-demand engagement with the solid tab member of a rotable collar - in which the configured spool section comprises a central cavity, open front and rear ends adapted for passage there through by a piercing needle, a flanged rib, a tab-engagement segment, and at least one notch disposed within the tab engagement segment - is radically different and completely unrelated in structure and operation to a preformed guide slot disposed within a rigid tube which has a circumferentially directed slot portion, and a longitudinally directed slot portion, and an inclined slot portion, as overtly required by the Vaillancort reference. No amount of subjective distortion can convert such a preformed guide slot into a configured spool section.

Applicant therefore affirms that the information content and value disclosed and/or implied by the Vaillancort '138 patent of record does not teach or suggest applicant's claimed subject matter with sufficient clarity or detail to establish that the instant invention existed in the prior art; and overtly denies that the present invention could or would be recognized by persons of ordinary skill in the art, given full knowledge and awareness of the Vaillancort '138 patent.

Equally important, applicant also maintains that the Vaillancort '138 patent of record can not suggest to those of ordinary skill in the relevant technical field that they should make applicant's claimed apparatus or utilize applicant's claimed invention for its intended purposes; nor does the '138 patent reveal or imply that, if one attempted to make or practice applicant's presently claimed invention, those of ordinary skill would have any reasonable expectation for success.

For all these reasons, applicant therefore respectfully submits that each and every amended claim now pending satisfies the novelty requirements of 35 USC 102(b), as well as the non-obvious requirement of 35 USC 103(a). Accordingly, applicant respectfully requests that the Examiners reconsider their stated position and withdraw this ground of rejection against the currently pending claims.

In sum, applicant has directly and forthrightly addressed the single basis of rejection stated in the most recently received (final) Official Action. In applicant's view, the single issue has been addressed and resolved completely. For these reasons, applicant respectfully submits and affirms that each of currently pending claims 3 and 9-10 are therefore allowable

In view of the above discussion and detailed review, applicant believes that this application is now in condition for allowance and reconsideration is respectfully requested. The Examiners are invited to call applicant's undersigned attorney should they feel that such a telephone call would further the prosecution of the present application.

Respectfully submitted,

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